


Hawaii Administrative Rule

Title 11

DEPARTMENT OF HEALTH

CHAPTER 15

MILK

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Historical Note: Chapter 11-15, Hawaii Administrative Rules, is based substantially upon Chapter 3, Public Health Regulations, Department of Health, State of Hawaii. [Eff **AUG 14 1989**]

§11-15-1 Purpose. The purpose of this chapter is to regulate the production, transportation, processing, handling, sampling, examination, grading, labeling, and sale of milk and milk products; the inspection of dairy herds, dairy farms, and milk plants; the issuing and revocation of permits to milk producers, haulers, and distributors, and the fixing of penalties. [Eff **AUG 14 1989**] (Auth: HRS §321-11) (Imp: HRS §§321-10, 321-11)

§11-15-2 Definitions. As used in this chapter:
"Adulterated milk and milk products" means any milk or milk product that is found to be adulterated within the meaning of section 328-9, HRS.

"Aseptically processed milk and milk products" means milk and milk products so thermally processed and hermetically sealed in a container in conformance with 21 CFR Part 113 and the provisions of this chapter as to render the product free of microorganisms capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

"Aseptic processing" or "aseptic processed" is the process to produce aseptically processed milk and milk products.

"Bulk milk pickup tanker" means a vehicle including the truck, tank, and those appurtenances necessary for its use, which is used by a milk hauler to transport bulk raw milk for pasteurization from a dairy farm to a transfer station, receiving station, or milk plant.

"Dairy farm" means any place or premise where one or more cows or goats are kept, and from which a part or all of the milk or milk product from the cows or goats is provided, sold, or offered for sale to a milk plant, transfer station, or receiving station.

"Department" means the department of health of the State of Hawaii.

"Director" means the director of health of the State of Hawaii or a duly authorized agent or representative.

"Hermetically sealed container" means a container which has been approved as a hermetically sealed container by the United States Food and Drug Administration or is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

"Homogenized" or "homogenization" means a milk or a milk product which has been treated to insure breakup of the fat globules to such an extent that, after forty-eight hours of quiescent storage at 45°F(70°C), no visible cream separation occurs on the milk or milk product and the fat percentage of the top one hundred milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than ten per cent from the fat percentage of the remaining milk or milk product as determined after thorough mixing.

"Milk distributor" means any person who offers for sale or sells to another any milk or milk products.

"Milk hauler" means any person who transports raw milk or raw milk products, or both, to or from a milk plant, receiving station, or transfer station.

"Milk plant" means any place, premise, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, bottled, or prepared for distribution.

"Milk producer" or "producer" means any person who operates a dairy farm and provides, sells, or offers any milk for sale to a milk plant, receiving station, or transfer station.

"Milk products" mean and include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured half-and-half, reconstituted or recombined milk and milk products, concentrated milk, concentrated milk products, skim milk, lowfat milk, frozen milk concentrate, eggnog, buttermilk, cultured milk, cultured lowfat milk, cultured skim milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified lowfat milk, acidified skim milk, reduced-sodium milk, reduced-sodium lowfat milk, reduced-sodium skim milk, lactose-reduced milk, lactose-reduced lowfat milk, lactose-reduced skim milk, imitation milk and milk products, substitute milk and milk products, aseptically processed and packaged milk and milk products as defined in this section, and milk, lowfat milk or skim milk with added safe and suitable microbial organisms.

This definition does not include milk products such as evaporated milk, evaporated skim milk, condensed milk (sweetened or unsweetened), dietary products (except as defined herein), infant formula, ice cream and other frozen desserts, dry milk products (except as defined herein), canned eggnog in a rigid metal container, butter or cheese except when they are combined with other substances to produce any pasteurized or aseptically processed milk or milk product defined in this section.

"Milk tank truck" means both a bulk milk pickup tanker and a milk transport tank.

"Milk transport tank" means a vehicle including the truck and tank used by a milk hauler to transport bulk shipments of milk from a transfer station, receiving station, or milk plant to another transfer station, receiving station, or milk plant.

"Misbranded milk and milk products" means products found to be misbranded within the meaning of section 328-10, HRS.

"Official laboratory" means a biological, chemical or physical laboratory which is under the supervision of the director.

"Officially designated laboratory" means a commercial laboratory or a milk industry laboratory certified by the director for the examination of producer samples of Grade "A" raw milk for pasteurization and commingled milk tank truck samples of raw milk for antibiotic residues and bacterial limits.

"Ordinance" means the Grade "A" Pasteurized Milk Ordinance, 1978, Recommendations of the United States Public Health Service, Food and Drug Administration, Publication No. 229, United States Department of Health, Education, and Welfare, as amended.

"Pasteurization" or "pasteurized" means the process of heating every particle of milk or milk product in properly designed and operated equipment to one of the temperatures given in the following table, and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
*145°F (63°C)	30 minutes
*161°F (72°C)	15 seconds
191°F (89°C)	1.0 second
194°F (90°C)	0.5 second
201°F (94°C)	0.1 second
204°F (96°C)	0.05 second
212°F (100°C)	0.01 second

*If the fat content of the milk product is ten per cent or more, or if the milk product contains added sweeteners, the specified temperature shall be increased by 5°F (3°C); provided, that eggnog shall be heated to at least the following temperature and time specifications:

Temperature	Time
155°F (69°C)	30 minutes
175°F (80°C)	25 seconds
180°F (83°C)	15 seconds

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the United States Food and Drug Administration to be equally efficient and which is approved by the director.

"Receiving station" means any place, premise, or establishment where raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

"Safe and suitable" means that the ingredient:

- (1) Performs an appropriate function in the food in which it is used;
- (2) Is used at a level no higher than necessary to achieve its intended purpose in that food; and
- (3) Is a food additive or color additive as defined in section 328-1, HRS, and is used in conformity with regulations established pursuant to section 409 or 706 of the Federal Food, Drug and Cosmetic Act.

"Sanitization" or "sanitizing," means the application of any effective method or substance to a clean surface for the destruction of pathogens and other organisms as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of consumers, and shall be acceptable to the director.

"Transfer station" means any place, premise, or establishment where milk or milk products are transferred directly from one transport tank to another.

"121 CFR" means Title 21 Code of Federal Regulations, effective April 1, 1989, unless otherwise specified in this chapter.

"Ultra high temperature," or "UHT" means that the milk or milk product has been subject to aseptic processing.

"Ultra-pasteurized" means a milk or milk product that has been thermally processed at or above 280°F (138°C) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

"Ungraded" means other than Grade "A." [Eff **AUG 14 1989**]
(Auth: HRS §§321-11, 328-8) (Imp: HRS §§328-11, 328-8)

§11-15-3 Standard of identity for milk. Milk shall comply with the requirements of 21 CFR section 131.110, with the following exceptions:

- (1) Milk in final package form shall have a thermister cryoscopic value of -0.525°H (degrees Hortvet) or below. Milk in final package form which has a thermister cryoscopic value of above -0.525°H shall be considered adulterated with added water; and
- (2) No adjustments to milk shall be made by the milk plant for the purpose of correcting deficiencies due to added water.
[Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-4 Standard of identity for goat milk. Goat milk is the lacteal secretion, practically Free from colostrum, obtained by the complete milking of healthy goats. The word "milk" shall be interpreted to include goat milk. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-5 Standard of identity for cream. Cream shall comply with the definition specified in 21 CFR section 131.3(a). [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-6 Standard of Identity for light cream. Light cream shall comply with the requirements of 21 CFR section 131.155. (Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 321-8)

§11-15-7 Standard of identity for light whipping cream. Light whipping cream shall comply with the requirements of 21 CFR section 131.157. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-8 Standard of identity for heavy cream. Heavy cream shall comply with the requirements of 21 CFR section 131.150. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-9 Standard of identity for whipped cream. Whipped cream shall comply with the requirements of 21 CFR sections 131.150 or 131.157 when air or gas has been incorporated, or 21 CFR section 131.25 for whipped cream products containing flavoring or sweetening. (Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-10 Standard of identity for sour cream. Sour cream shall comply with the requirements of 21 CFR section 131.160. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-11 Standard of identity for acidified sour cream. Acidified sour cream shall comply with the requirements of 21 CFR section 131.162. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-12 Standard of identity for half-and-half. Half-and-half shall comply with the requirements of 21 CFR section 131.180. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-13 Standard of identity for sour half-and-half. Sour half-and-half shall comply with the requirements of 21 CFR section 131.185. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-14 Standard of identity for acidified sour half-and-half. Acidified sour half-and-half shall comply with the requirements of 21 CFR section 131.187. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-15 Standard of identity for reconstituted or recombined milk and milk products. Reconstituted or recombined milk or milk products are

milk or milk products which result from the reconstituting or recombining of Grade "A" milk constituents with potable water and which comply with the standards of the corresponding milk or milk products. The name of the product is "Reconstituted _____," or "Recombined _____," the blank to be filled in with specific milk or milk product. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-16 Standard of identity for concentrated milk. Concentrated milk is an unsweetened fluid product resulting from the removal of a considerable portion of the water from the milk, which, when combined with potable water in accordance with instructions printed on the container, results in a product conforming with the milkfat and milk solids-not-fat levels of milk as defined in section 11-15-3. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 9 328-8)

§11-15-17 Standard of identity for concentrated milk products. Concentrated milk products shall include homogenized concentrated milk, concentrated skim milk, concentrated lowfat milk, and similar concentrated products made from concentrated milk or concentrated skim milk, and which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding milk products in this chapter. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-18 Standard of identity for frozen milk concentrate. Frozen milk concentrate is a frozen milk product with a composition of milkfat and milk solids-not-fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids-not-fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported, and sold in the frozen state. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-19 Standard of identity for skim milk. Skim milk shall comply with the requirements of 21 CFR section 131.143. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-20 Standard of identity for lowfat milk. Lowfat milk shall comply with the requirements of 21 CFR section 131-135. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-21 Standard of identity for eggnog. Eggnog shall comply with the requirements of 21 CFR section 131.170. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-22 Standard of Identity for buttermilk. Buttermilk is a fluid product resulting from the manufacture of butter from milk or cream. It contains less than 8.25 per cent of milk solids-not-fat. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-23 Standard of Identity for cultured milk. Cultured milk shall comply with the requirements of 21 CFR section 131.112. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-24 Standard of identity for cultured lowfat milk. Cultured lowfat shall comply with the requirements of 21 CFR section 131.138. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-25 Standard of Identity for cultured skim milk. Cultured skim milk shall comply with the requirements of 21 CFR section 131.146. [Eff **AUG 14 1989**] (Auth: HRS §§321-119 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-26 Standard of identity for yogurt. Yogurt shall comply with the requirements of 21 CFR section 131.200. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-27 Standard of Identity for lowfat Yogurt. Lowfat yogurt shall comply with the requirements of 21 CFR section 131.203. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-28 Standard of identity for nonfat yogurt. Nonfat yogurt shall comply with the requirements of 21 CFR section 131.2US. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-29 Standard of identity for acidified milk. Acidified milk shall comply with the requirements of 21 CFR section 131.111. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-30 Standard of identity for acidified lowfat milk. Acidified lowfat milk shall comply with the requirements of 21 CFR section 131.136. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-31 Standard of identity for acidified skim milk. Acidified skim milk shall comply with the requirements of 21 CFR section 131.144. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 321-8)

§11-15-32 Standard of identity for imitation milk and milk products. (a) An imitation milk or milk product is a milk or milk product in which there are combined one or more edible fats or oils, and conforms in all other respects to the definition and standard of identity for the product in semblance of which it is made; but is nutritionally inferior, as defined in 21 CFR section 101.3(e), to the milk or milk product in semblance of which it is made. If only one fat or oil is used it shall be a fat or oil other than milkfat. If more than one edible fat or oil is used in any such combination, one of them may be milkfat. Skimmed milk may be used. Each particular product shall contain not less than the minimum proportion of fat or oil as the minimum milkfat requirement for the milk or milk product in semblance of which it is made. Imitation milk and milk products shall be pasteurized or ultra-pasteurized.

(b) The name of the food is "Imitation Milk" or "Imitation _____," the blank to be filled in with the name of the milk or milk product in semblance of which the imitation milk product is made. The common names of each of the ingredients used in imitation milk and milk products shall be declared on the label as specified by the applicable sections of 21 CFR Part 101, except that the addition of nonfat dry milk as an ingredient shall not be called "skim milk," "skimmed milk," "nonfat milk," "reconstituted skim milk," or "concentrated skim milk." However, when Grade "A" skim milk, Grade "A" nonfat dry milk, or ungraded nonfat dry milk is used as an ingredient, the words "Grade "A" skim

milk," "Grade "A" nonfat dry milk," or "Ungraded nonfat dry milk," as the case may be, shall be indicated in the ingredient statement in letters of uniform size and importance relative to each of the ingredients and in no case may the word "Grade 'A'" be printed so as to be misleading. Imitation milk and milk products shall be ungraded. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-33 Standard of Identity for substitute milk and milk products. (a) A substitute milk or milk product is a milk or milk product in which there are combined one or more edible fats or oils, and which conforms in all other respects to the definition and standard of identity for the product in semblance of which it is made; and is not nutritionally inferior, as defined in 21 CFR section 101.3(e), to the milk and milk product in semblance of which it is made. If only one fat is used it shall be a fat or oil other than milkfat. If more than one edible fat or oil is used in any such combination, one of them may be milkfat. Skimmed milk may be used. Each particular product shall contain not less than the minimum proportion of fat or oil as the minimum milkfat requirement for the milk or milk product in semblance of which it is made. Substitute milk and milk products shall be pasteurized or ultra-pasteurized.

(b) The name of the food is "Substitute _____," the blank to be filled in with the specific milk or milk product. The common names of each of the ingredients used in substitute milk and milk products shall be declared on the label as specified by the applicable sections of 21 CFR Part 101, except that the addition of nonfat dry milk as an ingredient shall not be called "skim milk" "skimmed milk," "nonfat milk," "reconstituted skim milk," or "concentrated skim milk." However, when Grade "A" nonfat dry milk, Grade "A" skim milk, or ungraded nonfat dry milk is used as an ingredient, the words "Grade "A" nonfat dry milk," "Grade "A" skim milk," or "Ungraded nonfat dry milk," as the case may be, shall be indicated in the ingredient statement in letters of uniform size and importance relative to each of the ingredients and in no case may the word "Grade "A"" be printed so as to be misleading. Substitute milk and milk products shall be ungraded. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-34 Standard of identity for Grade "A" dry milk and whey products. Grade "A" dry milk and whey products are products which were produced for use in Grade "A" pasteurized or aseptically processed milk products and which were manufactured under the provisions of the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey-1978 Recommended Sanitation Ordinance for Condensed and Dry Milk Products and Condensed and Dry Whey Used in Grade "A" Pasteurized Milk Products, United States Department of Health, Education and Welfare, United States

Public Health Service, Food and Drug Administration. [Eff
AUG 14 1989] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11,
328-8)

§11-15-35 Standard of identity for reduced-sodium milk or reduced-sodium lowfat milk or reduced-sodium skim milk. Reduced-sodium milk or reduced-sodium lowfat milk or reduced-sodium skim milk is the product resulting from the treatment of milk, lowfat milk or skim milk as defined in this chapter by a process of passing the milk, lowfat milk or skim milk through an ion exchange resin process or any other process which has been recognized by the United States Food and Drug Administration that effectively reduces the sodium content of the product to less than ten milligrams in one hundred milliliters. [Eff
AUG 14 1989] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-36 Standard of identity for lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk. Lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk is the product resulting from the treatment of milk, lowfat milk or skim milk as defined in this chapter by the addition of safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and galactose so that the remaining lactose is less than thirty per cent of the lactose in milk, lowfat milk or skim milk. [Eff
AUG 14 1989] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-37 Adulterated or misbranded milk or milk products. (a) No person shall, within the State of Hawaii, produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell, any milk or milk product which is adulterated or misbranded. No person shall sell, offer, or have in his possession with intent to sell, any ungraded milk or milk products, except the ungraded milk or milk products specified in this chapter.

(b) Any adulterated or misbranded milk or milk product may be impounded, detained, embargoed, or seized by the director and d of in accordance with applicable laws or regulations. Any adulterated milk or milk product deemed by the director to constitute a health hazard shall be removed from sale by the manufacturer or distributor. [Eff
AUG 14 1989] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8, 328-25, 328-26, 328-27)

§11-15-38 Permits. (a) It shall be unlawful for any person who does not possess a permit from the director to bring into, send into, or receive

into the State of Hawaii for sale, or to sell, or offer for sale, or to have in storage any milk or milk products; provided that no permit shall be required of:

- 1) Grocery stores, restaurant, soda fountains, schools, institutions, and similar establishments where milk or milk products are served or sold at retail, but not processed or imported; or
- 2) Any person receiving or distributing imported aseptically processed milk and milk products which comply with the requirements of section 11-15-48; or
- 3) Any person receiving or distributing imported dry milk and whey products specified in section 11-15-34.

(b) Every milk producer, milk hauler, milk distributor, and each milk plant, receiving station and transfer station operator shall secure the permit by making written application on forms provided by the director. Upon receipt of such an application, the director shall make an inspection of the establishment and analyze the milk and milk products to determine compliance with the requirements of this chapter. When inspection and analysis of the milk and milk products reveal that the applicable requirements of this chapter have been met, the permit shall be issued to the applicant by the director. Only a person who complies with the requirements of this chapter shall be entitled to receive and retain a permit. The permit shall not be transferable with respect to persons or locations. The permit shall expire on June 30 of each year and an application to renew the permit shall be made prior to this date.

(c) A milk or milk product shall be deemed adulterated:

- (1) Whenever the director has reason to believe after inspection, investigation or sampling that the milk or milk product creates, or appears to create, an imminent health hazard to the public health;
- (2) Whenever the permittee's operational procedures prevent the collection of samples required by section 11-15-41;
- (3) Whenever the permittee has interfered with the director in the performance of the director's duties; or
- (4) In any case of a willful refusal to permit authorized inspection.

The permittee shall be given written notice specifying the particular violation and the milk or milk product shall not be offered for sale. When the violation has been corrected to the satisfaction of the director, the milk or milk product may be sold.

(d) Whenever the permitted has violated any of the requirements of this chapter, except as stipulated in subsection (c), the director may serve a written notice of intent to suspend the permit. Any person receiving a notice of intent to suspend the permit from the director may request a hearing pursuant to chapter 91, HRS.

A request for a hearing shall be in writing and submitted to the director not later than forty eight hours after receiving the intent to suspend notice. Upon receiving a request for a hearing by the permittee, the director shall proceed to a hearing to ascertain the facts of such

violation and upon evidence presented at the hearing shall affirm, modify, or rescind the intended suspension. As provided in chapter 91, HRS, the permittee shall be given written notice of hearing at least fifteen days before the hearing. If no request for a hearing is made, the permit shall be suspended.

In lieu of a hearing, any person whose permit has been suspended may make written application for reinstatement of the permit. The application shall include a statement signed by the applicant stating that in the applicant's opinion the conditions causing the suspension of the permit have been corrected. The application shall also include evidence supporting the applicant's opinion. The permit shall be reinstated when an inspection and analysis of the affected milk or milk product shows that the violation has been corrected to the satisfaction of the director.

(e) Upon repeated violation the director may revoke the permit following written notice to the permittee and an opportunity for a hearing as provided for in chapter 91, HRS. When a permit is revoked, a person may reapply for a permit pursuant to section 11-15-38(b).

(f) Any milk producer whose permit has been suspended may sell raw milk for manufacturing products such as cheese, ice cream, and frozen desserts; provided that the raw milk meets the standards for raw milk for manufacturing purposes in section 11-15-42. During the time the permit is suspended, the raw milk shall not be sold as Grade "A" raw milk or used to manufacture Grade "A" milk or milk products. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8, 328-11, 328-12)

§11-15-39 Labeling. (a) All bottles, containers, and packages enclosing milk or milk products defined in this chapter shall be labeled in accordance with the applicable requirements of this chapter, the Federal Food, Drug and Cosmetic Act as amended and the Federal Fair Packaging and Labeling Act and regulations developed thereunder.

(b) All bottles, containers, and packages enclosing milk or milk products except milk tank trucks, storage tanks, and cans of raw milk from individual dairy farms shall be conspicuously marked with:

- (1) The words "Grade A" except that this requirement shall not apply to imitation milk or milk products, substitute milk or milk products, and "ungraded" milk or milk products;
- (2) The word "pasteurized" if the contents are pasteurized;
- (3) The volume or proportion of water to be added for reconstituting or recombining in the case of concentrated milk or milk products;
- (4) The words "Keep refrigerated after opening" in the case of aseptically processed milk and milk products;
- (5) The words "ultra-pasteurized" if the milk or milk product has been ultra-pasteurized;
- (6) In the case of aseptically processed and packaged milk or milk products: "ultra high temperature" or "UHT;"
- (7) The word "Goat" preceding the name of the milk or milk product when the product is or is made from goat milk; and

- (8) The identity of the plant where pasteurized, ultra-pasteurized or aseptically processed.

(c) Every container of processed milk and milk product held in retail and wholesale stores, restaurants, schools, or similar establishments for sale shall be conspicuously and legibly marked by the milk plant with the designation of the month and day of the month after which the milk shall not be sold for human consumption. If the director determines that the quality of a milk or milk product deteriorates to the extent that the product becomes unmarketable prior to its designated shelf-life, the director shall notify the milk plant to conduct a full and complete review of the shelf-life of the product. If the review confirms that the designated shelf-life of the product is improper, the milk plant shall immediately shorten the designated shelf-life of the product in order to maintain the quality of the product throughout its intended shelf-life.

(d) All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.

(e) Milk tank trucks transporting raw milk and milk products to a milk plant from sources of supply not under the routine supervision of the director are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

- (1) Shipper's name, address, permit number;
- (2) Permit identification of hauler, if not employee of shipper;
- (3) Point of origin of shipment;
- (4) Tanker identity numbers;
- (5) Name of product;
- (6) Weight of product;
- (7) Grade of product;
- (8) Temperature of product;
- (9) Date of shipment;
- (10) Name of supervising regulatory agency at the point of origin; and
- (11) Whether the contents are raw, pasteurized, or in the case of cream, lowfat, or skim milk whether it has been heat-treated.

One copy of the shipping statement shall be retained by the consignor, one by the common carrier and at least two copies shall be delivered to the consignee with the shipment. The consignee shall forward at least one copy to the director.

Entries made on shipping statements by consignors or consignees shall be legible. When the Interstate shipment is derived from more than one point of origin, separate shipping statements for each of the sources involved shall accompany the shipment. Shipping statements shall be retained on file for a period of at least six months.

(f) All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.
[Eff

AUG 14 1989] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-40 Inspection of dairy farms and milk plants. (a) Each dairy farm, milk plant, receiving station, and transfer station whose milk or milk products are intended for consumption within the State of Hawaii shall be inspected by the director prior to the issuance of a permit. Following the issuance of a permit, each dairy farm and transfer station shall be inspected at least once every six months and each milk plant and receiving station shall be inspected at least once every three months. Should the violation of any requirement set forth in sections 11-15-42, 11-15-43, and 11-15-44 be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation has passed, but not before three days. This second inspection shall be used to determine compliance with the requirements of sections 11-15-42, 11-15-43, and 11-15-44. Any violation of the same requirements of sections 11-15-42, 11-15-43, and 11-15-44 on a second inspection shall be subject to permit suspension in accordance with section 11-15-38 or the institution of penalties as provided for in section 11-15-53, or both.

(b) When an inspection of a milk plant reveals that the process for manufacturing aseptically processed milk or milk products is less than that required for aseptic processing, it shall constitute an imminent health hazard and the director shall, in accordance with section 11-15-38, take immediate action to suspend the permit to produce aseptically processed milk or milk products.

(c) One copy of the inspection report shall be handed to the operator, or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. The inspection report shall not be defaced and shall be made available to the director upon request. An identical copy of the inspection report shall be filed with the records of the director.

(d) Every milk producer, hauler, distributor, or plant operator shall, upon request of the director, permit access to all parts of the establishment or facilities to determine compliance with the provisions of this chapter. A distributor or plant operator shall furnish the director, upon request, for official use only:

- (1) A true statement of the actual quantities of milk and milk products of each grade purchase⁴ and sold;
- (2) A list of all sources of the milk and milk products;
- (3) Records of inspections and tests; and
- (4) Pasteurization time and temperature records. [Eff **AUG 14 1989]** (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8, 328-22, 328-23)

§11-15-41 The examination of milk and milk products. (a) During any consecutive six months, at least four samples of raw milk for pasteurization shall be taken by the director from each producer and four

samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing shall be taken by the director from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing. In addition, during any consecutive six months, at least four samples of pasteurized and ultra-pasteurized milk and at least four samples of each milk product defined in this chapter, except aseptically processed milk or milk products, shall be taken by the director from every milk plant. Samples of milk and milk products shall be taken while in possession of the producer or distributor at any time prior to delivery to the store or consumer. The producer or distributor shall incorporate a system which will enable the director to collect required samples. Samples of milk and milk products from retail stores, food service establishments, and other places where milk and milk products are sold shall be examined periodically as determined by the director, and the results of the examination shall be used to determine compliance with sections 11-15-37, 11-15-39, and 11-15-47. Proprietors of such establishments shall furnish, upon the director's request, the names of all distributors from whom milk or milk products are obtained.

(b) Required bacterial counts, somatic cell counts, cooling temperature checks, and antibiotic tests shall be performed on raw milk for pasteurization. In addition, pesticide residue tests on raw milk shall be performed periodically as determined by the director. When commingled milk is tested, all producers shall be represented in the sample. All individual sources of milk shall be tested when test results on the commingled milk are positive. Required bacterial counts, antibiotic tests, coliform determination, phosphatase, and cooling temperature checks shall be performed on pasteurized milk and milk products. Pesticide, residue tests on pasteurized milk and milk products shall be performed periodically as determined by the director. All of the above tests and checks are to be performed by the director.

(c) Except for aseptically processed milk and milk products, whenever two of the last four consecutive bacterial counts, somatic cell counts, cooling temperatures, or coliform determinations taken on separate days exceed the limit of the standard for the milk or milk product as set forth in section 11-15-42, the director shall send a written notice informing the permittee that the permit may be suspended if an additional sample exceeds the standard. This notice shall remain in effect as long as two of the last four consecutive samples exceed the limit of the standard. An additional sample shall be taken within twenty-one days of the sending of the notice, but not before the lapse of three days.

Except for aseptically processed milk and milk products, whenever three of the last five consecutive bacterial counts, somatic cell counts, cooling temperatures, or coliform determinations taken on separate days exceed the limit of the standard for the milk or milk product

as set forth in section 11-15-42, the director shall send a written notice of intent to suspend the Grade "A" milk permit to the permittee as stipulated in section 11-15-38(d).

When more than one milk or milk product is included on a permit, the suspension shall apply to the milk or milk product in violation of this chapter, and shall not affect other milk and milk products which meet the requirements of this chapter.

(d) Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is known or suspected to be improper pasteurization, it shall be corrected by the permittee, and any milk or milk product involved shall not be offered for sale.

(e) Whenever an antibiotic or pesticide residue test exceeds the limit established by this chapter, the United States Food and Drug Administration, or the United States Environmental Protection Agency, an investigation shall be made to determine the cause, and the problem shall be corrected by the permittee. No milk shall be offered for sale until it is shown by a subsequent sample that the milk is free of antibiotic or pesticide residues or below the limit established for such residues.

(f) Whenever an aseptically processed milk or milk product is found to be unsterile due to under-processing, the director shall consider this to be an imminent hazard to public health. All product from the lot that was found to contain one or more unsterile units shall be removed from sale and disposed of as directed by the director. No aseptically processed milk and milk product shall be sold from the milk plant until it can be shown to the satisfaction of the director that the processes, equipment and procedures used are suitable for consistent production of a sterile product.

(g) Samples shall be analyzed by an official laboratory or an officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the fifteenth edition, 1985, of the "Standard Methods for the Examination of Dairy Products," a 1985 publication of the American Public Health Association, and the fourteenth edition, 1984, of the "Official Methods of Analyses of the Association of Official Analytical Chemists." Procedures and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories, 1978 Recommendations of the United States Public Health Service/Food and Drug Administration. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with Chapter 23 of the United States Food and Drug Administration's Bacteriological Analytical Manual, sixth edition, 1984. Examinations and tests shall be conducted to detect adulterants, as the director shall require. Assays of milk or milk products to which vitamins A or D have been added shall be made by the milk plant at least annually in a laboratory acceptable to the director for such examinations and at no cost to the director. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-6, 328-8, 328-9, 328-10, 328-22, 328-23, 328-24)

§11-15-42 Standards for milk and milk products. All Grade "A" raw milk for pasteurization, ultra-pasteurization or aseptic processing; all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products, all raw milk for manufacturing purposes, all reconstituted or recombined milk and milk products, all imitation milk and imitation milk products, and all substitute milk and milk products shall conform with the following chemical, bacteriological, and temperature standards. No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing, processing methods integral therewith, and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms. The chemical, bacteriological, and temperature standards shall be in accordance with the following:

Grade "A" Raw Milk for pasteurization, ultra-pasteurization, or aseptic processing	Temperature -	Cooled to 45°F(7°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 50°F(100°C).
	Bacterial limits -	Individual producer milk not to exceed one hundred thousand per milliliter; effective July 11, 1990, individual producer milk not to exceed seventy five thousand per milliliter; effective July 1, 1991, individual producer milk not to exceed fifty thousand per milliliter. Not to exceed three hundred thousand per milliliter as milk commingled with other producer milk prior to pasteurization; effective July 1, 1990,

		not to exceed two hundred thousand per milliliter as milk commingled with other producer milk prior to pasteurization; effective July 1, 1991, not to exceed one hundred fifty thousand per milliliter as milk commingled with other or milk prior to pasteurization.
	Antibiotics -	No zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for beta lactam residues; no zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for other inhibitors (OI).
	Somatic cell counts-	Individual producer milk: Not to exceed one million per milliliter; effective July 1, 1990, individual producer milk not to exceed 750,000 per milliliter.
Grade "A"	Temperature -	Cooled to 45°F(7°C) or less and maintained thereat.
pasteurized, or ultra-pasteurized, milk and milk products (including reconstituted or recombined milk and milk products)	Bacterial limits*-	Not to exceed twenty thousand per milliliter or per gram, as applicable; effective July 1, 1991, not to exceed ten thousand per milliliter or per gram, as applicable

	Coliform limit -	Not to exceed ten per milliliter or per gram, as applicable; provided that, in the case of bulk milk transport tank shipments, shall not exceed one hundred per milliliter.
	Phosphatase -	Less than one microgram per milliliter by the Scharer Rapid Method or equivalent.
	Antibiotics* -	No zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for beta lactam residues; no zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for other Inhibitors (OI).
Imitation milk or substitute milk and milk products	Temperature -	Cooled to 450°F or less and maintained there-at.
	Bacterial limits*-	Not to exceed thirty thousand per milliliter or per gram, as applicable.
	Coliform limit -	Not to exceed ten per or per milliliter gram, as applicable.
	Phosphatase -	Less than one microgram per milliliter by Sharer Rapid Method or equivalent.
	Antibiotics -	No zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for beta lactam residues; no

		zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for other inhibitors (OI).
Raw milk for manufacturing purposes	Temperature -	Cooled to 45°F(7°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 500°F(100°C).
	Bacterial limits -	Individual producer milk not to exceed four hundred thousand per milliliter.
	Antibiotics -	No zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for beta lactam residues; no zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for other inhibitors (OI).
Grade "A" pasteurized cultured milk product	Temperature -	Cooled to 45°F(7°C) or less and maintained thereat.
	Coliform limit -	Not to exceed ten per milliliter or per gram, as applicable.
	Phosphatase -	Less than one microgram per milliliter by Scharer Rapid Method or equivalent.
Grade "A" aseptically processed milk and milk products	Temperature -	None.
	Bacterial limits -	No growth by test specified in section 11-15-41(g).

Antibiotics -	No zone equal to or greater than sixteen millimeters using the <u>Bacillus stearothermophilus</u> disc assay method for beta lactam residues; no zone equal to or greater than sixteen millimeters the <u>Bacillus stearothermophilus</u> disc assay method or other inhibitors (OI).
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*Not applicable to cultured products

**Not applicable to eggnog or eggnog products.

[Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-43 Sanitation requirements for Grade "A" raw milk for pasteurization, ultra-pasteurization or aseptic processing. (a) Cows which show evidence of secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment, and the milk shall be discarded. Cows treated with, or cows which have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgment of the director, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the director may direct.

(b) A milking barn, stable, or parlor shall be provided on all farms in which the milking herd shall be housed during milking operations. The areas used for milking purposes shall:

- (1) Have floors constructed of concrete or of equally impervious material;
- (2) Have walls and ceilings which are smooth, painted or finished in an approved manner, in good repair, and ceiling dust-tight;
- (3) Have separate stalls or pens for horses, calves, and bulls;
- (4) Be provided with natural or artificial light, well distributed for day or night milking;
- (5) Provide sufficient air space and air circulation to prevent condensation and excessive odors;
- (6) Not be over-crowded; and
- (7) Have dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed.

(c) The interior of the milking barn, stable, or parlor shall be kept clean. Floors, walls, windows, pipelines, and equipment shall be free of filth or litter, and shall be clean. Swine and fowl shall be kept out of the milking barn.

(d) The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes; provided that in loafing or cattle-housing areas, cow droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the cow's udder and flanks. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard.

(e) A milkhouse or room of sufficient size shall be provided, in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted, except as provided in section 11-15-43(1). In addition:

- (1) The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system;
- (2) The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner;
- (3) The milkhouse shall have adequate natural or artificial light and be well ventilated;
- (4) The milkhouse shall be used for no other purpose than milkhouse operations. There shall be no direct opening into any barn, stable, or into a room used for domestic purposes; provided that a direct opening between the milkhouse and milking barn, stable, or parlor is permitted when a tight-fitting self-closing solid door hinged to be single or double acting is provided;
- (5) Potable water under pressure shall be piped into the milkhouse;
- (6) The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities;
- (7) When a transportation tank is used for the cooling and/or storage of milk on the dairy farm, such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control, and general maintenance; and
- (8) Electrical switches which are used to control the milking and agitating operations in farm bulk tanks shall be properly identified.

(f) The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, and

equipment, and other milk room equipment shall be clean. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals, fowl, and vermin.

(g) Every dairy farm shall be provided with one or more toilets, conveniently located and properly constructed, operated, and maintained in a sanitary manner. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply.

(h) Potable water for milkhouse and milking operations shall be from an approved supply properly located, protected, and operated, and shall be easily accessible adequate, and of a safe, sanitary quality.

(i) All multi-use containers equipment, and utensils used in the handling, storing, or transporting of milk shall be made of smooth, nonabsorbent, corrosion-resistant, non-toxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils, and equipment shall be in good repair. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported, stored, and handled in a sanitary manner and shall comply with the applicable requirements of section 11-15-44(m). Articles intended for single service use shall not be reused. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of sections 11-15-44(l) and (m).

(j) The product-contact surfaces of all multi-use containers equipment, and utensils used in the handling, storage, or transportation of milk shall be cleaned after each usage.

(k) The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

(l) All containers, utensils, and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solution shall be stored to assure complete drainage and shall be protected from contamination prior to use. Pipeline milking equipment, such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, and milk pumps, which are designed for mechanical cleaning may be stored in the milking barn or parlor provided this equipment is designed, installed, and operated to protect the product and solution contact surfaces from contamination at all times.

(m) After sanitization, all containers, utensils, and equipment shall be handled in such a manner so as to prevent contamination of any product-contact surface.

(n) Milking shall be done in the milking barn, stable, or parlor. The flanks, udders, bellies, and tails of all milking cows shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking cows shall be cleaned and treated with a sanitizing solution just prior to the time of milking, and shall be relatively dry before milking. Wet hand milking is prohibited.

(o) Surcingles, milk stools, and anti-kickers shall be kept clean and stored above the floor.

(p) Milking and milkhouse operations, equipment, and facilities shall be located and conducted to prevent any contamination of the milk, equipment, containers, and utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination.

(q) Adequate hand-washing facilities shall be provided, including a lavatory fixture with potable running water, soap or detergent, and individual sanitary towels, in or convenient to the milkhouse, milking barn, stable, parlor, or flush toilet.

(r) Hands shall be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities. Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

(s) Raw milk for pasteurization shall be cooled to 45°F(7°C) or less within two hours after milking provided that the blend temperature after the first milking and subsequent milkings does not exceed 50°F(100°C).

(t) Vehicles used to transport milk in from the dairy farm to the milk plant or receiving station shall be constructed and operated to protect their contents from sun and contamination. Such vehicles shall be kept clean, inside and out; and no substance capable of contaminating milk shall be transported with milk.

(u) Effective measures shall be taken to prevent the contamination of milk containers, equipment, and utensils by insects and rodents, and by the chemicals used to control such vermin. Milkrooms shall be free of insects and rodents. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-44 Sanitation requirements for Grade "A" pasteurized, ultra-pasteurized and aseptically processed milk and milk products.

(a) A receiving station shall comply with subsections (c) to (q), (s), (v) and (x), except that the partitioning requirement of subsection (g) shall not apply.

(b) A transfer station shall comply with subsections (c), (f), (h) through (p), (v) and (x); and, as climatic and operating conditions require, the applicable provisions of subsections (d) and (e); provided that in every case, overhead protection shall be provided. Facilities for the cleaning and sanitizing of bulk transport tanks shall comply with subsections (c), (d), (h) through (q), (v) and (x); and as climatic and operating conditions require, the applicable provisions of subsections (d) and (e); provided that in every case, overhead protection shall be provided.

(c) The floors of all rooms in which milk or milk products are processed, handled, or stored, or in which milk containers, equipment, and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleaned material; and shall be smooth, properly sloped, provided with trapped drains, and kept in good repair; provided that cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits; provided further that storage rooms for storing dry ingredients or packaging materials need not be provided with drains; and the floors may be constructed of tightly-joined wood.

(d) Walls and ceilings of rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed, shall have a smooth washable, light-colored surface, and in good repair.

(e) Effective means shall be provided to prevent the access of insects, rodents and other vermin. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

(f) All rooms in which milk and milk products are handled, processed, or stored or in which milk containers, equipment, and utensils are washed shall be well lighted and well ventilated.

(g) There shall be separate rooms for:

- (1) The pasteurizing, processing, cooling, and packaging of milk and milk products;
- (2) The cleaning of milk cans, bottles and cases;
- (3) Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks; and
- (4) Receiving cans of milk and milk products in plants receiving such cans.

Rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed or stored, shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

(h) Every milk plant shall be provided with toilet facilities conforming with the regulations of the department. Toilet rooms shall not open directly into any room in which milk or milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms, and fixtures shall be kept clean, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.

(i) Potable water for milk plant purposes shall be from an approved supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

Convenient hand-washing facilities shall be provided, including hot and cold or warm running potable water, dispensed through a mixing valve and faucet, soap, and individual sanitary towels or other approved hand-drying devices. Hand-washing facilities shall be kept clean and in good repair.

(k) All rooms in which milk and milk products are handled, processed, or stored, or in which containers, utensils, or equipment are washed or stored, shall be kept clean, neat, and free of evidence of insects, rodents and other vermin. Only equipment directly related to processing operations or to handling of containers, utensils, and equipment shall be permitted in the pasteurizing, processing, cooling, packaging, and bulk milk storage rooms.

(l) All sanitary piping, fittings, and connections which are exposed to milk and milk products, or from which liquids may drip, drain, or be drawn into milk or milk products, shall consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.

(m) All multiuse containers and equipment with which milk or milk products come into contact shall be of smooth, impervious, corrosion-resistant, non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which milk or milk products come in contact shall be non-toxic, and shall have been manufactured, packaged, transported, and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

(n) The product-contact surfaces of all multiuse containers, utensils, and equipment used in the transportation, processing, handling, and storage of milk and milk products shall be effectively cleaned and sanitized before each use. The piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products beyond the final heat treatment process shall be cleaned and sterilized before any aseptically processed milk or milk product is packaged and shall be re-sterilized whenever any unsterile product has contaminated it. The term sterilized when applied to piping, equipment and containers used for milk and milk products shall mean the condition achieved by application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.

(o) After cleaning, all multiuse milk or milk product containers, utensils, and equipment shall be transported and stored to assure complete drainage, and shall be protected from contamination before use.

(p) Single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk and milk products shall be purchased and stored in sanitary tubes, wrappings, or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

(q) Milk plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, equipment, containers, and utensils. All milk or milk products

or ingredients which have been spilled, overflowed, or leaked shall be discarded. The processing or handling of products other than milk and milk products in the pasteurization plant shall be performed to preclude the contamination of the milk and milk products. The storage, handling, and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products or the product-contact surfaces of all equipment, containers, and utensils.

(r) Pasteurization or ultra-pasteurization shall be performed as defined in section 11-15-2. Aseptic processing shall be performed in accordance with 21 CFR Part 113 and the administrative procedures of item 16p(C), 16p(D), and 16p(E) of the ordinance.

(s) All raw milk and milk products shall be maintained at 45°F(7°C) or less until processed. All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging in approved equipment to a temperature of 45°F(7°C) or less. On delivery vehicles, the temperature of milk and milk products shall not exceed 50°F(10°C). Every room or tank in which milk or milk products are stored shall be equipped with an accurate thermometer. Aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

(t) Bottling and packaging of milk and milk products shall be done at the place of pasteurization in approved mechanical equipment.

(u) Capping or closing of milk and milk product containers shall be done in a sanitary manner by approved mechanical capping or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

(v) Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing his hands. All persons engaged in the processing, pasteurization, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils shall wear clean outer garments. All persons, while engaged in the processing of milk or milk products, shall wear adequate hair coverings and shall not use tobacco.

(w) All vehicles used for transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 45°F(7°C) or less, and are protected from sun, freezing, and from contamination. However, while actively engaged in the delivery of the milk and milk products where the air temperature inside the vehicle may rise, a product temperature rise to 50°F is allowed for the short period of time during delivery.

(x) Milk plant surroundings shall be kept neat, clean, and free from conditions which might attract or harbor flies, other insects, rodents and other vermin, or which otherwise constitute a nuisance. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 323-8)

§11-15-45 Animal health. (a) All milk for pasteurization shall be from herds which are located in a modified accredited tuberculosis area as determined by the United States Department of Agriculture; provided that herds located in an area that fails to maintain such an accredited status shall have been accredited by the United States Department of Agriculture as tuberculosis free, or shall have passed an annual tuberculosis test.

(b) All milk for pasteurization shall be from herds under a brucellosis eradication program which meets one of the following conditions:

- (1) Located in a certified brucellosis-free area as defined by the United States Department of Agriculture and enrolled in the testing program for the area;
- (2) Located in a modified certified brucellosis area as defined by the United States Department of Agriculture and enrolled in the testing program for the area;
- (3) Meets United States Department of Agriculture requirements for an individually certified brucellosis free herd;
- (4) Participating in a milk ring testing program which is conducted on a continuing basis at intervals of not less than every three months or more than every six months with individual blood tests on all animals in herds showing suspicious reactions to the milk ring test; or
- (5) Has an individual blood agglutination test annually with an allowable maximum grade period not exceed two months.

(c) For diseases other than brucellosis and tuberculosis, the director shall require such physical, chemical, or bacteriological tests as the director deems necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employment of an official agency of the State of Hawaii. Any diseased animal disclosed by the test shall be disposed of as required by applicable state laws. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-46 Milk and milk products which may be sold. Only Grade "A" pasteurized milk and milk products shall be sold to the final consumer, or to restaurants, soda fountains, grocery stores, or similar establishments; provided that:

- (1) Ungraded substitute milk or milk products, or ungraded imitation milk or milk products, may likewise be sold, provided

the products are prepared and pasteurized in a milk plant conforming with the sanitary requirements of this chapter; or

- (2) In an emergency, the sale of pasteurized, ultra-pasteurized or aseptically processed milk and milk products made with ungraded milk or milk products may be authorized by the director in which case the products shall be labeled "ungraded." [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-47 Transferring; delivery container; cooling. (a) Except as permitted in this section, no milk producer or distributor shall transfer milk or fluid milk products from one container or tank truck to another on the street, in any vehicle, store, or in any place except in a milk plant, receiving stations, transfer station, or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

(b) It shall be unlawful to sell or serve any milk or fluid milk product except in the individual, original container received from the distributor, or from an approved bulk dispenser, or by a method approved by the director; provided that this requirement shall not apply to milk for mixed drinks requiring less than one-half pint of milk, or to cream, whipped cream, or half-and-half which is consumed on the premises and which may be served from the original container of not more than one-half gallon capacity, or from a bulk dispenser approved for such service by the director.

(c) It shall be unlawful to sell or serve any pasteurized milk or fluid milk product which has not been maintained at a temperature of 45°F (7°C) or less. If containers of pasteurized milk or fluid milk products are stored in ice, the storage container shall be properly drained.

(d) It shall be the duty of all persons to whom milk or fluid milk products are delivered to clean thoroughly the containers in which the milk or fluid milk products are delivered before returning the containers.

(e) Apparatus, containers, equipment and utensils used in the handling, storage, processing or transportation of milk or fluid milk products shall not be used for any other purpose without the permission of the director. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-43 Milk and milk products from points beyond the limits of routine inspection. Milk and milk products not produced in the State of Hawaii may be sold in the State of Hawaii, provided they are produced and pasteurized, ultra-pasteurized or aseptically processed under regulations which are substantially equivalent to this chapter and have been awarded an acceptable milk sanitation compliance and enforcement rating made by a state milk sanitation rating officer certified by the United States Food and Drug Administration. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-49 Future dairy farms and milk plants. Properly prepared plans for all milkhouses, milking barns, stables, parlors, transfer stations, receiving stations, and milk plants regulated under this chapter which are hereafter constructed, reconstructed, or extensively altered, shall be submitted to the director for written approval before work is begun. A copy of the approved plans shall be retained by the permittee for inspection by the director. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-50 Personnel health. No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any dairy farm or milk plant in any capacity which brings that person into contact with the production, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils; and no dairy farm or milk plant operator shall employ in any such capacity any such person, or any person suspected of having any disease in a communicable form, or of being a carrier of such disease. Any producer or distributor of milk or milk products, upon whose dairy farm, or in whose milk plant any communicable disease occurs, or who suspects that any employee has contracted any disease in a communicable form, or has become a carrier of such disease, shall notify the director immediately. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-51 Procedure when infection suspected. When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of milk or milk products, the director may require any or all of the following measures:

- (1) The immediate exclusion of that person from milk handling;
- (2) The immediate exclusion of the milk supply concerned from distribution and use; and
- (3) Adequate medical and bacteriological examination of the person, of his associates, and of his and their body discharges. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-52 Administration and enforcement. This chapter, insofar as it follows the Grade "A" Pasteurized Milk ordinance, 1978 Recommendations of the United States Public Health Service, Food and Drug Administration, Publication No. 229, United States Department of Health, Education, and Welfare, as amended, shall be administered and enforced in accordance with the administrative procedures contained therein. Where mandatory compliance with the provisions of the appendices is specified in the ordinance, the provisions shall be deemed a requirement of this chapter. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

§11-15-52.5 Inspection of U.S. Food and Drug, Administration regulations. The ordinance and Title 21 Code of Federal Regulations, as referenced in this chapter, may be inspected by the public during regular business hours at the Food Products Section, Sanitation Branch, Department of Health, 591 Ala Moana Boulevard, Honolulu, Hawaii.

§11-15-53 Penalty. (a) Any person who violates any provision of this chapter shall be guilty of a misdemeanor. Each and every violation of the provisions of this chapter shall constitute a separate offense.

(b) In addition to any other administrative or judicial remedy provided in this chapter, the director may fine any person who violates any provision of this chapter a fine or penalty of not more than \$10,000 for each separate offense. Factors to be considered in imposing the administrative penalty include the nature and history of the violation and of any prior violation, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the administrative penalty imposed, the director need only show that notice was given, a hearing was held, or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and that the penalty remains unpaid.

(c) The director may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent any violation of this chapter. [Eff **AUG 14 1989**] (Auth: HRS §§321-8, 321-9, 321-10, 321-11, 321-18, 328-30, 328-31) (Imp: HRS §§321-11, 328-8, 328-22, 328-25, 328-28, 328-29, 328-30, 328-31)

§11-15-54 Repeal of rules. All versions of chapter 3, Public Health Regulations, as they existed on March 15, 1980, are repealed. [Eff **AUG 14 1989**] (Auth: HRS §§321-9, 321-10, 321-11) (Imp: HRS §§321-9, 321-10, 321-11)

§11-15-55 to §11-15-99 Reserved.

§11-15-100 Severability. Should any section, paragraph, sentence, clause, phrase, or application of this chapter be declared unconstitutional or invalid for any reason, the remaining sections, paragraphs, sentences, clauses, phrases, or applications of this chapter shall not be affected. [Eff **AUG 14 1989**] (Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)

The Department of Health authorized the repeal of Chapter 3, Public Health Regulations, and the adoption of Chapter 15 of Title 11, Hawaii Administrative Rules, on Milk following public hearings held on Oahu on Wednesday, May 10, 1989, on Hawaii on Monday, May 22, 1989, on Kauai on, Wednesday, May 24, 1989, and on Maui on Tuesday, May 23, 1989, after public notice was given in the Honolulu Advertiser on April 12, 1989, in the Hawaii Tribune-Herald on April 24, 1989, in the Garden Isle on April 24, 1989, and in the Maui News on April 24, 1989.

Chapter 15, of Title 11, Administrative Rules, and the repeal of Chapter 3, Public Health Regulations, shall take effect ten days after filing with the Lieutenant Governor.

JOHN C. LEWIN, M.D.
Director
Department of Health

APPROVED:

JOHN WAIHEE
Governor
State of Hawaii

Dated: JUL 28 1989

APPROVED AS TO FORM:

Deputy Attorney General

Filed: _____

Effective Date: _____

NOTICE OF CHANGE

8/8/89

The citation of authority for and list of sections implemented by §11-15-52.5, Hawaii Administrative Rule, should read as follows:

(Auth: HRS §§321-11, 328-8) (Imp: HRS §§321-11, 328-8)